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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,343

03/26/2004

William A. Cook

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WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP
111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

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MAIL DATE

DELIVERY MODE

07/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/811,343	Applicant(s) COOK ET AL.	
	Examiner Paul B. Prebilic	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-54 and 64-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-54 and 64-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/4/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak et al (US 5,695,998) in view of O'Leary (US 5,298,222) or Kemp (US 5,460,962). Badylak discloses a submucosal tissue source which is first delaminated into tunica muscularis and tunica mucosa (i.e. submucosal tissue) prior to being disinfected; see column 3, lines 3-44. The present claim language requires a step of separation after the disinfectant treatment rather than before as Badylak discloses. However, O'Leary (see columns 1 and 2, particularly column 1, lines 14-21 where the tissue is treated with an antibiotic (i.e. a disinfectant) prior to further processing) or Kemp (see column 3, lines 21 et seq., particularly column 5, lines 12-24 where a sterilized one inch sample is removed from the one foot tissue source) teaches that it was known to sterilize similar tissues prior to further mechanical processing. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to disinfect the submucosal tissue source of Badylak prior to delamination for the same reason that O'Leary does the same; see column 1, lines 34-39.

With regard to claims 28 and 29, Applicants are directed to see column 1, lines 41-59 of Badylak.

With regard to claim 30, Applicants are directed to see column 8, lines 28-30 of Badylak.

With regard to claim 37, Applicants are directed to see column 7, lines 55-64.

With regard to claims 31-33, Applicants are directed to see Table 1 on column 8 where hydrogen peroxide is the oxidizing agent or peroxy compound. Acetyl peroxide is the organic peroxy compound of claim 33.

With regard to claim 42 and 43, the solutions set forth in Example 2 of Badylak should inherently have the same pH as the claimed solution because they are the same as the claimed solutions. Alternatively, the Examiner asserts that the pH is Badylak is within the claimed range; see MPEP 2112 which is incorporated herein by reference.

With regard to claim 46, the Applicants are directed to see column 8, lines 28-30 of Badylak.

With regard to claims 48, 49, and 51, the Applicants are directed to see Table 1 on column 8 where hydrogen peroxide is the oxidizing agent or peroxy compound as claimed. Acetyl peroxide is the organic peroxy compound of claim 51.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 64-66 are rejected under 35 U.S.C. 102(e) as anticipated by Badylak et al (US 5,695,998) or Abraham et al (US 5,993,844), or, in the alternative, under 35 U.S.C. 103(a) as obvious over Badylak et al (US 5,695,998) or Abraham et al (US 5,993,844) in view of O'Leary (US 5,298,222) or Kemp (US 5,460,962). Badylak discloses a submucosal tissue source which is first delaminated into tunica muscularis and tunica mucosa (i.e. submucosal tissue) prior to being disinfected; see column 3, lines 3-44. Similarly, Abraham discloses providing a submucosal tissue source that is treated with a disinfecting agent and separated from the submucosal layer; see Example 1, column 4, line 49 to column 5, line 6, and column 8, line 55 to column 9, line 13. The claimed properties of the "wherein" clauses, in claim 64, are considered inherent to Badylak or Abraham because the tissue is treated in a manner identical to the claimed invention. Abraham discloses that the resulting tissue is sterile and endotoxin free; see column 5, lines 2-6. Since the sterilization step can be performed before or after the separation step, the claimed method is fully disclosed by either Badylak or Abraham.

Alternatively, if one interprets the present claim language as requiring a step of separation after the disinfectant treatment rather than before as Badylak or Abraham discloses, then the Badylak or Abraham do not fully disclosed the claimed method. However, O'Leary (see columns 1 and 2, particularly column 1, lines 14-21 where the tissue is treated with an antibiotic (i.e. a disinfectant) prior to further processing) or Kemp (see column 3, lines 21 et seq., particularly column 5, lines 12-24 where a sterilized one inch sample is removed from the one foot tissue source) teaches that it

was known to sterilize similar tissues prior to further mechanical processing. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to disinfect the submucosal tissue source of Badylak or Abraham prior to delamination for the same reason that O'Leary does the same; see column 1, lines 34-39.

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham, Badylak, O'Leary, and Kemp as applied to claims 64-66 above, and further in view of Badylak (US 5,554,389). Abraham or Badylak do not disclose the use of urinary tract tissue as the tissue source as claimed. However, Badylak ('389) teaches that the same was known to the art; see the abstract. For this reason, the Examiner asserts that it would have been *prima facie* obvious to an ordinary artisan to utilize urinary tract tissue as the tissue source for the same reasons that Badylak ('389) utilizes the same.

Response to Arguments

Applicant's arguments filed April 4, 2008 have been fully considered but they are not persuasive.

The Applicants argue that Kemp and O'Leary do not teach the missing limitation of Badylak on page 9 of the response. However, the Examiner asserts that Kemp does teach further mechanical processing on column 5, lines 12-24 where a one inch segment is removed from a one foot sterilized tissue source. Likewise, O'Leary teaches that an antibiotic (i.e. a type of disinfectant) is utilized to treat the tissue prior to further processing; see column 1, lines 22-28. For this reason, the arguments are considered unpersuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774